Prospective Randomized Clinical Comparison of 2 Dental Implant Navigation Systems

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Purpose: *The aim of this prospective randomized study was to compare the clinical accuracy of and surgical time required for mandibular dental implant placement with 2 computer-assisted navigation systems using pre- and postoperative computerized tomographic (CT) data.* ***Materials and Methods:*** *In 16 patients with edentulous mandibles, 4 interforaminal implants per patient were placed with computer-assisted navigation. The implant bed was prepared by transmucosal drilling without mucosal punching. Patients were randomly allocated to either the VISIT navigation system (32 implants; 8 patients) or the Medtronic StealthStation Treon navigation system (32 implants; 8 patients). Pre- and postoperative CT scans were matched using the normalized mutual information 3D registration algorithm to compare preplanned and final implant positions. Operation room time was recorded from start of preoperative preparations to end of surgery.* ***Results:*** *All implants were placed as planned; there were no intra- or postoperative complications. Average implant deviation errors of 0.7 mm and 0.9 mm were recorded for the VISIT and StealthStation Treon navigation systems, respectively. Timing revealed an average operation room time of 81.3 ± 15.8 minutes for the VISIT navigation system and 60 ± 10.4 minutes for the StealthStation Treon navigation system.* ***Conclusions:*** *The accuracy of implant bed preparation and placement was similar in both systems. Both navigation systems are equally precise in a clinical environment. However, total operation room time was 25% shorter with the StealthStation Treon navigation system, probably because of the faster tracking system update rate.*
(Controlled Clinical Trial) INT J ORAL MAXILLOFAC IMPLANTS 2007;22:785–790

Key words: *accuracy, computer-assisted navigation, dental implants*

The use of computerized tomography (CT) scanning in dental implant planning enables optimum use of available bone volume. Templates[1–5] or surgical navigation systems[6–11] allow precise placement of implants according to preoperative planning data. The need for minimal invasive techniques to improve accurate positioning and biomechanical stability of implants (and thus success rates) has led to the introduction of computer-aided navigation in the field of oral implantology.[7,11,12] The decision to use computer-aided navigation in dental implant placement depends on the expected benefit from the procedure as well as on the technical expenditure necessary to achieve that goal. Ewers et al[13] have shown that the medical benefit outweighs the expenses in selected cases. Other authors have also shown that computer-assisted planning in oral implant surgery largely outperforms manual planning based on 2-dimensional (2D) dental CT images and also helps to avoid complications such as mandibular nerve damage, sinus perforation, fenestration, and dehiscence.[14,15] Commercial navigation systems for implant dentistry allow real-time visualization of drill movements as a graphical overlay on CT images on a screen.

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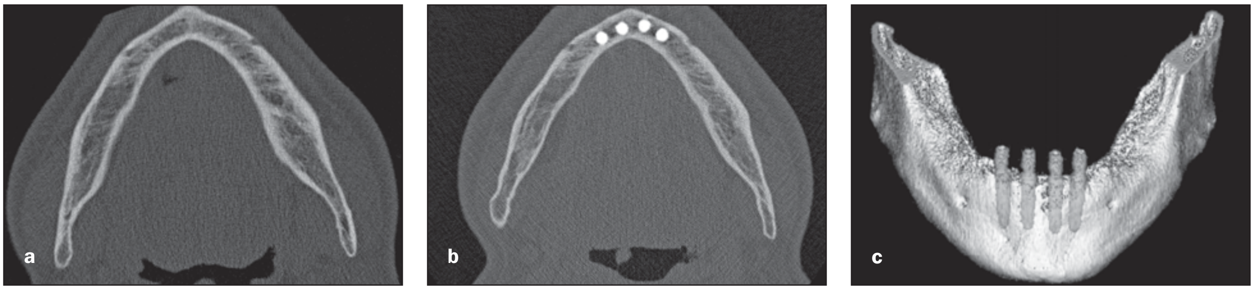

Figs 1a to 1c *(a and b)* Pre- and postoperative CT scans of a 63-year-old male patient. *(c)* A 3-dimensional rendering of the postoperative CT scan with implants in place.

The VISIT navigation system[6,9–11] is an experimental navigation device specially designed for implant dentistry. For comparison, the commercial StealthStation Treon, a neurosurgical navigation system, was adapted for dental implant placement. The difference between the navigation systems lies in the user interface and the tracking systems. Their accuracy is primarily defined by the CT data[11] and the registration procedure.[16]

The aim of this study was to compare accuracy of placement and surgical time required for the placement of mandibular dental implants with 2 different types of computer-assisted navigation systems using the same CT data acquisition and registration procedure.

MATERIALS AND METHODS

Sixteen patients with mandibular edentulism (duration > 1 year) and adequate bone height (> 15 mm) and width (> 5 mm) in the anterior mandible were included in this study. Four screw-shaped Ankylos implants (Dentsply Friadent, Mannheim, Germany) were placed in each interforaminal region. Before treatment, the patients were randomly allocated to 1 of 2 navigation systems. Eight patients (7 men, 1 woman) were operated with the VISIT navigation system (University of Vienna, General Hospital, Vienna, Austria),[6] and 8 patients (4 men, 4 women) received treatment with the StealthStation Treon navigation system (Medtronic, Minneapolis, MN). A single surgeon (GW) experienced in navigated implant surgery performed all surgical procedures.

The work flow within both the VISIT and StealthStation Treon systems consists of the following steps[12,16]:

1. Importation of CT data
2. On-screen drawing of the dental arc and the inferior alveolar nerve
3. Planning of implant position and orientation in selected 3-dimensional (3D) views
4. Patient registration (by means of intraosseous microscrews)
5. Intraoperative navigation

CT Data Acquisition

Images were acquired using a Philips Brilliance 16 Power CT (Philips MX8000 IDT, Philips Medical Systems, Eindhoven, The Netherlands). Voxel size was 0.17 $\times$ 0.17 $\times$ 0.75 mm on a 1024 $\times$ 1024 matrix, with a field-of-view of 175 $\times$ 175 mm. Volume images were transferred to the navigation systems using the standard DICOM protocol. A typical situation in a 63-year-old male patient is presented in Figs 1a to 1c.

Navigation Systems

The StealthStation Treon software does not yet feature a specialized implant dentistry interface, but its interface for placement of spinal implants can be used for this purpose.[17] The VISIT navigation system[6,9–11] was specially designed for implant dentistry. In both systems the optimal implant positions were planned on a preoperative CT data set. Prior to image acquisition, 4 titanium microscrews were placed transmucosally into mandibular bone under local anesthesia. These screws acted as fiducial markers on the CT images and in the operating room for reliable and accurate registration of the patient relative to the CT.[16] These microscrews were removed immediately after implant placement. During dental implant placement, both the patient position and the position of the surgical drill were tracked by optical tracking systems. The navigation system was connected to the patient as well as the surgical drill through a dynamic reference frame (Fig 2). The VISIT system uses the Flashpoint 5000 as an optical tracking device (Image Guided Technologies, Boulder, CO), while the StealthStation Treon navigation system uses the passive Polaris tracking device (Northern Digital, Waterloo, ON, Canada). Optical tracking tools

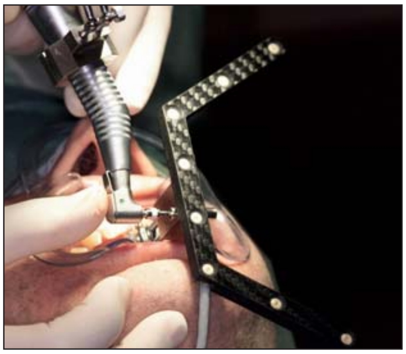

Fig 2 *(left)* Tracking device. The patient and the surgical drill were both connected to the navigation system through a dynamic reference frame.

Fig 3 *(right)* Initial preparation of the implant bed. The overlying ridge mucosa and bone were penetrated with a 2-mm pilot drill.

were either specifically designed for implant placement or were adapted from standard instrumentation. Details on the registration process, the design of tools for optical tracking, and the various factors influencing the accuracy of navigation systems have been published in earlier reports.[6,16,18]

Navigation added time to the surgical procedure. Time was required to mount the position measurement sensor to the mandible and to place the intraoral fiducial markers for registration prior to surgery. Intraoperative calibration of the drilling handpiece was also necessary. The duration of the navigated implantation procedure was measured from start of preoperative preparation in the operating room to end of surgery in 5-minute intervals for both navigation systems.

Implant System

Implant placement was carried out under local anesthesia using the Ankylos implant system (Dentsply Friadent Ceramed, Lakewood, CO). The mucosa was penetrated without flap elevation or mucosal punching. The study protocol did not allow direct visualization of the bone surface during surgery. The implant bed was prepared in 3 phases: mucosal penetration, cortical and spongy bone preparation. First, the mucosa was penetrated with a 2-mm pilot drill (Fig 3). Cortical penetration was then performed perpendicular to the alveolar crest, avoiding drill shift. Implant bed preparation consisted of pilot drilling with a 2-mm drill followed by definitive implant bed preparation using 3.5-mm, 4.5-mm, or 5.5-mm drills. The drilling sequence was followed by tapping and insertion of screw-shaped Ankylos implants. After the implants had been inserted with a handpiece, a torque wrench was used to complete the seating; finally, implant stability was measured (Periotest; Siemens, Bensheim, Germany).

Evaluation

The pre- and postoperative CT scans of the patients were matched using the normalized mutual information 3D registration algorithm of the Analyze AVW 6.0 software (Biomedical Imaging Resource; Mayo Clinic, Rochester, MN) on a conventional personal computer. This registration algorithm aligns the CT scans relative to each other to compensate for variations in patient position. The result is a mathematical transform conveying the coordinate system of the preoperative CT scan and the implant position planning to the postoperative CT scan. After this 3D registration, the preoperative planning data were transformed to the postoperative CT, and distances between preplanned and final implant positions were compared on the corresponding slices.[9–11] After alignment of the CT scans, a number of positions were measured and compared on the pre- and postoperative scans. These were *(a)* distance from the implant tip normal to the labial and lingual cortices of the mandible and *(b)* distance from the implant platform normal to the labial and lingual cortices.

RESULTS

At the time of implant placement, the mean age of the patients treated with the VISIT navigation system was 63.4 ± 7.7 years (range, 56 to 77 years); the mean age of those treated with the StealthStation Treon navigation system was 61.3 ± 6.3 years (range, 55 to 75 years). Transmucosal implantation with the VISIT navigation system resulted in an average error of 0.7 mm (range, 0.3 to 2.0 mm; variance, 0.03 mm^2). With the StealthStation Treon navigation system, an average error of 0.9 mm (range, 0.0 to 3.4 mm; variance, 0.05 mm^2) was found. Labial and lingual deviations at the tip and the platform of the implants are summarized in Table 1 and Fig 4. The labio-lingual deviations in both systems were similar except for the lingual platform (Fig 4). The higher lingual base deviation recorded for StealthStation Treon navigation system was due to an exceptional deviation of 1 implant in

Table 1 Navigation Accuracy for Transmucosal Implant Placement

	Labial deviation			Lingual deviation		
	Average	SD	Range	Average	SD	Range
VISIT navigation system						
Implant top	0.6	0.2	0.3 to 0.9	0.7	0.3	0.3 to 1.0
Implant platform	1.0	0.5	0.3 to 2.0	0.7	0.3	0.3 to 1.2
Treon						
Implant top	0.8	0.6	0.0 to 2.0	0.7	0.5	0.0 to 1.6
Implant platform	1.0	0.5	0.1 to 2.4	1.2	0.8	0.1 to 3.4

The difference between planned and final implant position was assessed on pre- and postoperative CT scans as the distance normal to the labial cortex of the mandible and the distance normal to the lingual cortex.

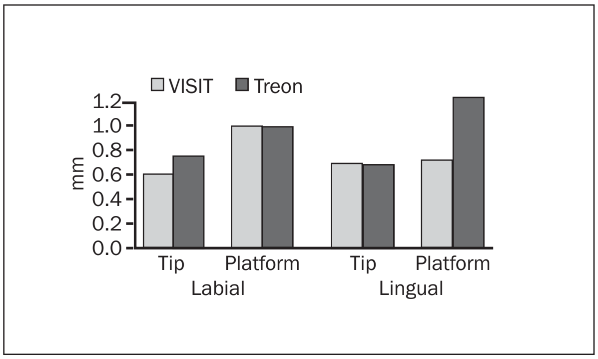

Fig 4 Mean labial and lingual deviations after transmucosal implantation with the VISIT and the StealthStation Treon navigation systems.

Table 2 Time Used for Preoperative Preparation and Navigated Implantation

Patient	Preoperative preparation (min)	Navigated implantation (min)	Total
VISIT navigation system			
1	20	90	110
2	20	80	100
3	15	55	70
4	15	60	75
5	15	65	80
6	10	70	80
7	15	50	65
8	15	55	70
Mean ± SD	15.6 ± 3.2	65.6 ± 13.7	81.3 ± 15.8
Treon			
1	10	55	65
2	10	45	55
3	15	65	80
4	10	50	60
5	10	55	65
6	10	45	55
7	5	40	45
8	10	45	55
Mean ± SD	10.0 ± 2.7	50.0 ± 8.0	60 ± 10.4

Preoperative preparations included calibration of the drill and registration of the patient prior to implantation. The time needed for the preoperative preparation and the navigated implantation was measured in intervals of 5 minutes.

this group due to irregularities of the alveolar crest. However, no perforation of the mandibular cortex or damage to the mandibular canal was observed with either system; there were no intra- or postoperative complications. An average operation room time of 81.3 ± 15.8 minutes for the VISIT and 60 ± 10.4 minutes for the StealthStation Treon navigation system was recorded (Table 2).

DISCUSSION

During the last decade, image-guidance systems have become a valuable tool in several surgical disciplines,[19,20] including oral implant surgery.[9,11,12,16] Like the application of drilling templates,[4] image guidance is mainly intended to transfer a preoperatively planned insertion concept into a clinical environment. In contrast to drilling templates, image guidance provides the surgeon with multi-dimensional real-time information regarding the anatomy, thus allowing modifications during surgery without loss of guidance.[21]

The insertion of dental implants requires an accurate position, angulation, and insertion procedure to achieve results that are satisfying biomechanically, functionally, phonetically, and esthetically. Many clinical studies on conventional[22,23] and computer-aided navigated[11–13] dental implant insertion have been published. Several commercial navigation systems are currently available; some are adapted for dental implant placement, while others, such as the VISIT navigation system,[6,9–11] the Virtual Implant Navigator (Medlibre Forschungs, Munich, Germany), or the RoboDent and the LapDoc Systems (Robodent, Berlin, Germany) were specially developed for dental implant surgery. Most of the differences between navigation systems lies in the user interface and the tracking system accuracy and update rate.[11] The overall accuracy is also dependent on the CT data[11] and registration procedure.[6] The effectiveness of navigation systems depends on their accuracy,[24] while their efficiency depends on the speed of the technology.

The clinical performance and accuracy of 2 navigation systems, the VISIT navigation system and the StealthStation Treon navigation system, were compared in a clinical environment using the same CT data acquisition and registration procedure.

Navigation added time to the surgical procedure. The Polaris tracker system of the StealthStation Treon navigation system was superior to the VISIT navigation system in terms of update rate and therefore was found to need less operation room time.

The accuracy of both systems used in this study appears better than those of earlier studies.[10,11] The main reasons are probably the availability of high-resolution CT and fixation of the patient's head during CT acquisition, as first suggested by Wagner et al.[25] In addition, the accuracy of placement has also been reported to depend on the accuracy of the reference body, which should be detectable in a reproducible manner on CT images and surgery.[26] Therefore, the use of metallic intraosseous fiducial markers may also have contributed to improved accuracy. An additional intervention under local anesthesia is needed for the placement of these fiducial markers; however, their removal during implant surgery required only seconds and did not add to postoperative morbidity.

The accuracy of both systems used in this study is superior to earlier reports,[10,11] although the sample size of this study is too small to be subjected to tests of significance. However, this improvement could be clinically relevant, especially in cases where surgeons with less technical experience use the navigation system. The clinical outcome after the application of image-guided surgery in the course of implant dentistry depends not only on the performance of the surgical navigation system but also on the skills of the surgeon to interpret positional data displayed on the computer screen during drilling of the implant socket[10] and also on the implant system used. Several cycles of drilling and widening are required to prepare the socket; each additional cycle increases the possibility of deviation. The accuracy of the navigation system can therefore be best evaluated at the implant platform.[10] Whereas earlier studies have reported more deviations at the implant tip than at the platform,[10,11] more deviations at the platform were recorded in the present study (Table 1). Implant bed preparation in this study was accomplished without mucosal elevation and reflection; the alveolar crest was not directly visible to the surgeon. Therefore, the eccentric shift at the beginning of implant bed preparation, which led to more deviations at the platform, could not be prevented, because the Ankylos system was not designed for implant bed preparation without mucosal punching.[27] This may also have been responsible for the major lingual deviation recorded for an implant placed in an area of irregular alveolar crest. Future development in computer-assisted flapless transmucosal implant surgery might focus on alternative drilling instrumentation, such as piezoelectric drills or even robotic systems, to facilitate accurate dental implant placement.

CONCLUSION

The navigation systems used in this study were clinically almost equally precise. For preoperative preparation and intraoperative navigation, the StealthStation Treon navigation system was 25% faster than the VISIT navigation system, probably because of its superior tracking system. However, further clinical evaluation and comparison of navigation systems is required.

ACKNOWLEGMENT

The development of VISIT was supported by FWF grant P12464 – MED and OeNB 8450. Analyze AVW was provided courtesy of Dr R. A. Robb, Biomedical Imaging Resource, Mayo Clinic, Rochester, Minnesota.

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